IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

United States of America ex rel. Dr. Lewis Eastlick, Plaintiff-Relator v. William Thomas Odom, II, M.D. Defendant.	C/A No. 3:20-cv-00803-CMC **Opinion and Order**

This *qui tam* action under the False Claims Act ("FCA"), 31 U.S.C. § 3729 (a)(1)(A)–(B), involves allegations a physician filed thousands of false and/or fraudulent claims for reimbursement of medical services under the Medicare Part B program. The action is currently before the court on cross motions for summary judgment, and the court has carefully reviewed the voluminous filings in this regard.

I. Relevant Background

In 1965, Congress established the Medicare program as Title XVIII of the Social Security Act, commonly known as the Medicare Act, to address the serious need for health insurance coverage for the aged and disabled. 42 U.S.C. §§ 1395–1395lll. The Medicare program is divided into four parts denoted by the letters A through D. 42 C.F.R. § 400.202. Medicare Part B is the only part at issue in the instant case. 42 U.S.C. §§ 1395j–1395w-6. Generally speaking, Medicare Part B covers out-patient medical care such as physician services, the provision of medical

supplies, diagnostic services, and laboratory and x-ray tests.[1] *Id.* §§ 1395k, 1395w-4, 1395x(s)(1); 42 C.F.R. §§ 407.2; 410.10(a), (d)–(e), (g); 410.20(a).

To fully apprehend the factual and legal issues at hand, a journey into the dense forest of statutes and regulations forming some of the operational intricacies of Medicare Part B is necessary. In general, Medicare Part B covers only "reasonable and necessary" out-patient medical care "for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Under the Medicare Act, a physician who furnishes medical services under Medicare is a "supplier," *id.* §1395x(d), and, with exceptions not relevant here, "[t]he term 'physician services' means professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls," *id.* 1395x(q). *See also* 42 C.F.R. § 400.202 (defining "Supplier," for purposes of Medicare, as "a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare"); (defining "Provider," for purposes of Medicare, as, *inter alia*, a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, or a home health agency).

Congress entrusted the Secretary of the United States Department of Health and Human Services ("the Secretary") to administer Medicare Part B. *Id.* §§ 1395ff(a)(1), 1395hh(a)(1). The Secretary in turn delegated much of this responsibility to its own internal agency known as the Centers for Medicare and Medicaid Services ("CMS"). *See* Centers for Medicare & Medicaid

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[1] Medicare Part A is the hospital insurance program, Medicare Part C provides the choice of Medicare benefits through the Medicare Advantage plans, and Medicare Part D is the voluntary prescription drug benefit program. 42 C.F.R. § 400.202.

Services; Statement of Organization, Functions and Delegations of Authority; Reorganization Order, 66 Fed. Reg. 35,437-03 (July 5, 2001). CMS, in turn, contracts with private third-parties known as Medicare Administrative Contractors ("MACs") to process claims under Medicare Part B. 42 U.S.C. §§ 1395u(a), 1395kk-1. MACs are authorized to process and pay Medicare Part B claims within a specified geographic jurisdiction. 42 C.F.R. §§ 421.400, 401, 404. At all relevant times during the instant case, the MAC authorized to process claims by Medicare Part B providers and suppliers in South Carolina was Palmetto GBA. ECF No. 52-3 at 2.

MACs "typically authorize payment of claims immediately upon receipt of the claims, so long as the claims do not contain glaring irregularities." *Gulfcoast Med. Supply v. Sec'y, Dep't of Health & Human Servs.*, 468 F.3d 1347, 1349 (11th Cir. 2006). Post-payment audits conducted by recovery audit contractors ("RACs") under the Medicare Integrity Program are intended to catch any improper payments or overpayments. 42 U.S.C. § 1395ddd(a), (f)(7), (h); 42 C.F.R. § 421.304. In the case of an observed abnormal billing pattern, RACs are authorized to use probe sampling in conducting the audit. 42 U.S.C. § 1395ddd(f)(8). Additionally, in the case of sustained or a high level of payment error, extrapolation is permissible "to determine overpayment amounts to be recovered by recoupment, offset, or otherwise . . . ." *Id.* § 1395ddd(f)(3). Notably, MACs can also perform the same functions as RACs, so long as they do not duplicate those functions. *Id.* 1395kk-1(a)(4)(H), (a)(5). The upshot is a MAC can conduct a post-payment audit of claims so long as a RAC is not already doing so.

With the aim of consistency in coverage determinations, Medicare's national payment policies for covered items or services are set forth in national coverage determinations ("NCDs"),

which are formal decisions by the Secretary regarding whether and under what circumstances Medicare will cover a particular item or service. 42 U.S.C. § 1395ff(a)(1), (f)(1)(B); 42 C.F.R. § 405.1060(a)(1). National coverage determinations "do[] not include a determination of what code, if any, is assigned to a particular item or service covered . . . or a determination with respect to the amount of payment made for a particular item or service so covered." 42 U.S.C. § 1395ff(f)(1)(B). National coverage determinations are binding on both MACs and administrative law judges ("ALJs") who preside over Medicare coverage appeals. 42 U.S.C. § 1395ff(f)(1)(A)(i); 42 C.F.R § 405.1060(a)(4).

In contrast, local coverage determinations ("LCDs") are decisions by a particular MAC and govern Medicare coverage for a particular item or service within the MAC's geographic jurisdiction. 42 U.S.C. § 1395ff(f)(2)(B). Absent a governing LCD, a MAC reviewing a claim for Medicare reimbursement applies the "not reasonable and necessary" coverage exclusion and other coverage criteria to the factual circumstances at hand. Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63692-1, 63693 (Nov. 7, 2003) (final rule). ALJs are not bound by LCDs but must afford an LCD substantial deference if it applies to a particular claim. 42 C.F.R. § 405.1062(a).

A physician who wants to bill Medicare for treating a patient covered by Medicare Part B must enroll in Medicare as a supplier and receive a Medicare National Provider Identifier ("Medicare NPI"). *Become A Medicare Provider or Supplier*, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Become-a-Medicare-Provider-or-Supplier (last visited October 28, 2021). The enrolled physician then files a claim for

reimbursement of his or her services covered by Medicare Part B by submitting, in most cases, an electronic version of the CMS-1500 claim form. 42 C.F.R. § 424.32(a)(1), (b); *Medicare Claims Processing Manual Chapter 26 - Completing and Processing Form CMS-1500 Data Set*, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf (last visited October 28, 2021). The CMS-1500 claim form requires the claimant to include his Medicare NPI, the appropriate diagnostic code, and the appropriate billing code for the services provided. 42 C.F.R. § 424.32(a)(2); 45 C.F.R. §§ 160.103; 162.1002(a)(5), (c). As participants in the Medicare program, Medicare suppliers have a duty to familiarize themselves "with the legal requirements for cost reimbursement." *See Heckler v. Cmty. Health Servs.*, 467 U.S. 51, 64 (1984).

In 2002, billing codes developed by the American Medical Association known as Current Procedural Terminology Codes ("CPT Codes") became a valid billing code-set by which healthcare providers may bill the federal government for reimbursement under Medicare. *See* 45 C.F.R. § 162.1002(a)(5), (c) (providing CPT Codes developed and maintained by the American Medical Association are a valid code-set by which healthcare providers may bill for reimbursement under Medicare); *see also Hooper v. United Healthcare Ins. Co.*, 694 F. App'x 902, 908–09 (4th Cir. 2017) (describing history of the CPT codebook developed by the American Medical Association); The American Medical Association, *CPT Overview and Code Approval*, https://www.ama-assn.org/practice-management/cpt/cpt-overview-and-code-approval (last visited October 28, 2021). As will be detailed shortly, two different CPT Codes are at issue in the pending cross motions for summary judgment.

As the claims process goes, a MAC makes an initial determination as to whether an item or service qualifies for reimbursement within its jurisdictional geographic region. 42 C.F.R. § 405.920. Any claimant dissatisfied with the initial determination may file an administrative appeal. *Id.* § 405.904. The administrative appeal process consists of up to four steps: (1) a redetermination by the MAC which originally denied the claim; (2) review by a different contractor known as a "qualified independent contractor" or "QIC"; (3) a hearing before an ALJ; and (4) review by the Medicare Appeals Council ("the Council"), an adjudicatory body within the United States Department of Health and Human Services. *Id.* § 405.904(a)(2), (b). *See also Agendia, Inc. v. Becerra*, 4 F.4th 896, 897 (9th Cir. 2021) (listing the four steps of administrative appeal process for claims under Medicare Parts A and B). Once a claimant has exhausted the administrative appeal process, the claimant can seek judicial review of the Secretary's "final decision" in federal district court. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A).

CPT Codes 64450 and 95909 are at issue in the cross motions for summary judgment, and CPT Code 76942 is additionally at issue in Dr. Odom's motion for summary judgment. CPT Code 64450 is used to bill for "Introduction/Injection of Anesthetic Agent (Nerve Block), Diagnostic or Therapeutic Procedures on the Somatic Nerves." https://www.aapc.com/codes/cpt-codes/64450 (last visited October 28, 2021). According to the summary on the website of the American Association of Professional Coders, with respect to CPT Code 64450: "The provider injects an anesthetic agent, steroid, or both close to a peripheral nerve or branch not represented by another code. Report this code for one or more injections during a single procedure." *Id.* CPT Code 95909 is used to bill for reimbursement of "Nerve Conduction Tests."

https://www.aapc.com/codes/cpt-codes/95909 (last visited October 28, 2021). According to the summary on the website of the American Association of Professional Coders, "[i]n this procedure, the provider performs five or six nerve conduction studies, a diagnostic test to evaluate the function, especially the ability of electrical conduction of the motor and sensory nerves of the human body." *Id.* CPT Code 76942 is used to bill for a physician's diagnostic ultrasound guidance to guide needle placement for a nonvascular procedure (*e.g.*, needle biopsy, aspiration, and injection). *CPT code 76492: Ultrasonic Guidance Needle Placement NonVascular*, https://www.americanmedicalcoding.com/cpt-code-76942 (last visited October 28, 2021).

As part of his defense in this case, Dr. Odom asserts he performed the medical services underlying every Medicare Part B claim at issue pursuant to a Medicare qualifying clinical trial. With respect to clinical trials, NCD 310.1, promulgated by the Secretary, provides "Medicare covers the routine costs of **qualifying** clinical trials . . ., as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials." ECF No. 56-1 at 4 (emphasis added) (version number 2 with effective date of July 9, 2007). A clinical trial is qualifying if it meets ten criteria set forth in NCD 310.1. ECF No. 56-1 at 5. For example, the trial must not unjustifiably duplicate existing studies and must comply with Federal regulations relating to the protection of human subjects. *Id.*

Some clinical trials are deemed automatically qualifying based upon a presumption they meet all ten criteria. *Id.* at 6. For example, a clinical trial funded by the National Institutes of Health is deemed automatically qualifying. *Id.* Other clinical trials are qualifying if they are required through the NCD process. *Id.* In all other cases, for a clinical trial to receive Medicare

coverage of routine costs, (1) it must meet the ten qualifying criteria; (2) "the trial's lead principal investigator [must] certif[y] that the trial meets the qualifying criteria," and (3) the principal investigator must enroll the trial in the Medicare clinical trials registry. ECF No. 56-1 at 6. The clinical trials registry found at the website ClinicalTrials.gov, a resource provided by the United States National Library of Medicine, is considered the Medicare clinical trials registry. *ClinicalTrials.gov Background*, https://clinicaltrials.gov/ct2/about-site/background (last visited October 28, 2021); *Center for Medicare and Medicaid Services (CMS) and Reporting of ClinicalTrials.gov Identifiers on Claims*, https://clinicaltrials.gov/ct2/manage-recs/resources#CMS (last visited October 28, 2021). ClinicalTrials.com houses "a database of privately and publicly funded clinical studies conducted around the world." https://clinicaltrials.gov (last visited October 28, 2021). In the case of an automatically qualifying clinical trial, neither its lead principal investigator nor any other principal investigator must certify it meets the qualifying criteria. ECF No. 56-1 at 6. Nonetheless, a principal investigator must still enroll the trial in the clinical trials registry found at ClinicalTrials.gov. *Id.*

Upon enrollment, the United States National Library of Medicine assigns the trial a National Clinical Trial ("NCT") identifier number. Rosemarie Hakim *et al.*, *Mandatory Reporting of the 8-Digit National Clinical Trial Identifier Number*, https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number.pdf (last visited October 28, 2021). Notably, the webpage for any particular clinical trial in ClinicalTrials.gov's clinical trial registry displays the following disclaimer: "The safety and scientific validity of this study is

the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government." *See*, *e.g.*, https://clinicaltrials.gov/ct2/show/NCT01979367?term=NCT+01979367&draw=2&rank=1 (last visited October 28, 2021).

II. The FCA's Legal Framework

Under subsection (a)(1)(A), the FCA imposes civil liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . ." to the Government. 31 U.S.C. § 3729(a)(1)(A). Under subsection (a)(1)(B), the FCA imposes liability on "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . " for payment by the Government. Both subsections have the following four elements in common: (1) falsity; (2) causation; (3) knowledge, *i.e.*, scienter; and (4) materiality. *Cf. U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 913 (4th Cir. 2003) (holding so under materially similar pre-2009 version of FCA). The distinctive element of subsection (a)(1)(A) is the defendant's presentment or causing presentment of a false or fraudulent claim for payment to the Government ("the element of presentment"), while the distinctive element of subsection (a)(1)(B) is the defendant's making, using, or causing to be made or used a false record or statement relating to a false or fraudulent claim for payment to the Government ("the element of a false record or statement"). Notably, although subsection (a)(1)(B) does not require the defendant himself to have presented a false claim to the Government, "a plaintiff asserting an FCA claim [under this subsection] is still required to show that a false claim was submitted to the government." *United States ex rel. Grant*

v. United Airlines, Inc., 912 F.3d 190, 200 (4th Cir. 2018); *see also id.* at 196 ("In order for a false statement to be actionable under either subsection of the FCA, it must be made as part of a false or fraudulent claim.").

Under the FCA's scienter requirement, "knowingly" encompasses actual knowledge of the false information, deliberate ignorance of its truth or falsity, and reckless disregard of its truth or falsity. 31 U.S.C. § 3729(b)(1)(A). "The purpose of the FCA's scienter requirement is to avoid punishing 'honest mistakes or incorrect claims submitted through mere negligence.'" *United States ex rel. v. Tuomey*, 792 F.3d 364, 381 (4th Cir. 2015) (quoting *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010)). A false record or statement is material to a false or fraudulent claim for payment by the Government if it has "the tendency to influence, or [is] capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Further, the false statement or fraudulent conduct alleged "must represent an objective falsehood." *United States ex rel. Wilson v. Kellog Brown & Root, Inc.*, 525 F.3d 370, 376–77 (4th Cir. 2008). As a result, "'imprecise statements or differences in interpretation growing out of a disputed legal question are . . . not false under the FCA.'" *Id.* (quoting *United States v. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)).

"[I]n certain circumstances, the implied false certification theory can be a basis for liability." *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1995 (2016). "A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the [FCA]." *Id.* at 1996. "The implied certification theory can be a basis for liability, at least where two conditions

are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001. Notably, given concerns about fair notice and open-ended liability under the FCA, the Supreme Court has called upon courts to strictly enforce the FCA's materiality and scienter requirements, which the Supreme Court has described as "rigorous." *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2002 (2016).

III. Procedural History

Having this statutory and regulatory background in mind, the court now recounts the procedural history of the instant case thus far. Plaintiff-Relator Dr. Lewis Eastlick ("Relator") filed a two-count complaint ("the Complaint") in this case on February 21, 2020, seeking recovery on behalf of the United States of America ("the Government") for alleged violations of the FCA. In Count I of the Complaint, Relator alleges William Thomas Odom, II, M.D. ("Dr. Odom"), a board-certified anesthesiologist, violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting or causing to be presented thousands of false or fraudulent claims to the Government under Medicare Part B for payment of medically unnecessary healthcare services he allegedly performed in years 2014, 2016, and 2017. ECF No. 1 at 16-17. In Count II, Relator alleges Dr. Odom violated 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, or causing to be made, or using false records or statements material to thousands of false or fraudulent claims presented to the Government under Medicare Part B for payment of medically unnecessary healthcare services he allegedly performed in years 2014, 2016, and 2017.

Both counts involve the same four sets of claims for payment Dr. Odom allegedly presented to the Government for medical services he provided patients as a supplier under Medicare Part B. They are reported as follows in the order the court will address them in this Opinion and Order. In set one ("Claim-Set One"), Relator alleges Dr. Odom presented 14,541 claims for payment under CPT Code 64450 for nerve-block injections he performed on 94 patients, averaging 155 injections per patient, in 2016, for which the Government paid him a total of $476,715. ECF No. 1 at 10. In set two ("Claim-Set Two"), Relator alleges Dr. Odom presented 12,749 claims for payment under CPT Code 64450 for nerve block injections he performed on 110 patients, averaging 116 injections per patient, in 2017, for which the Government paid him $411,321. *Id.* In set three ("Claim-Set Three"), Relator alleges Dr. Odom presented 624 claims for payment under CPT Code 95909 for five or six nerve-conduction studies he performed on 105 patients, averaging six sets of studies per patient, in 2016, for which the Government paid him $67,211. ECF No. 1 at 14. In set four ("Claim-Set Four"), Relator alleges Dr. Odom presented 1,377 claims for payment under CPT Code 76942 for ultrasonic guidance imaging supervision and interpretation for needle insertion he performed on 279 patients, averaging 4.9 claims per patient, in 2014, for which the government paid him $70,659. ECF No. 1 at 16.

With respect to CPT Code 64450, involved in Claim-Sets One and Two, Relator alleges "If . . . [Dr.] Odom actually performed the number of procedures per patient that he claimed then he unnecessarily risked patient harm." *Id.* at 10. Further, Relator alleges the claims Dr. Odom presented under CPT Code 64450 "reflect a pattern in which patients risk excessive frequency for unnecessary and potentially risky injections." *Id.* "For these reasons," Relator alleges, "many or

most of the claims submitted by Dr. Odom for CPT [Code] 64450 are false." *Id.* With respect to CPT Code 95909, involved in Claim-Set Three, Relator alleges the national average is one set of nerve-conduction studies per patient. *Id.* at 13. Relator further alleges, based upon Relator's knowledge and experience as a board-certified orthopedic surgeon who routinely performs hand surgery, the high level of repetitions per patient "indicate the initial service was performed incorrectly (and thus a false claim), or that the first or the following services were not medically necessary." *Id.* Relator also alleges, in Relator's "experience and professional opinion, it is both implausible and beyond the standards of care that 105 patients arrived in [Dr. Odom's] office, all of whom required 5 to 6 studies, none more and none less, and that it was necessary to have patients return again and again to repeat the diagnostic, and that this was 'reasonable and necessary for the diagnosis' and that such studies were made in accordance with accepted standards of medical practice for the treatment of the patient's conditions, and not simply to increase the [Dr. Odom's] profits." *Id.* at 14–15.

As required by the FCA, the matter was initially maintained under seal to allow the Government to investigate the claims alleged and elect whether to intervene. 31 U.S.C. § 3730(b)(2). On May 22, 2020, the Government declined intervention. *Id.* § 3730(b)(4); ECF No. 10. The court then ordered the seal lifted on all documents in the case, thus allowing for service of process on Dr. Odom. 31 U.S.C. § 3730(b)(2), (4); ECF No. 11.

On June 19, 2020, Dr. Odom filed his initial motion to dismiss (Initial Motion to Dismiss) under Rules 8(a)(2), 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure and the FCA's public-disclosure bar, 31 U.S.C. § 3730(e)(4). ECF No. 18. Dr. Odom declared he is board

certified in anesthesiology and is a Principal Investigator in a study to "demonstrate the non-inferiority of devices in question (Axon II 250 Hz small pain fiber (spf) testing device[)], Anodyne/MIRE, TENS, NBPM (Nerve Block pain management) for lower extremity neurological ischemia." *Id.* at 6. He argued this explains the high volume of medical claims filed by him as identified by Relator. Further, Dr. Odom contended this entire action should be rendered moot because he and his medical practice are "already experiencing collection activity for the same services referenced in" Relator's complaint. *Id.* at 7. According to Dr. Odom, the current action "attempts to duplicate the government's current collection efforts." *Id.* Dr. Odom further asserted this case should be dismissed pursuant to the FCA's public-disclosure bar, which, in general, is triggered when the fraud allegations existed in the public domain before a *qui tam* relator filed suit, and Relator failed to satisfy the original source exception to overcome this bar. *Id.* at 7-8. Finally, Dr. Odom asserted Relator failed to plead his allegations of fraud with sufficient particularity to satisfy Rule 9(b) of the Federal Rules of Civil Procedure ("Rule 9(b)") and failed to allege facts which, if accepted as true, state a claim for relief that is plausible on its face as required by Rule 8(a)(2) of the Federal Rules of Civil Procedure ("Rule 8(a)(2)"). As part of this motion, Dr. Odom also sought attorneys' fees and costs on the ground the allegations in the Complaint are clearly frivolous. *Id.* at 24.

Relator responded in opposition, arguing repayment of alleged false claims might reduce but would not eliminate Dr. Odom's liability in this case, as the FCA provides for treble damages and civil penalties. 31 U.S.C. § 3729(a); ECF No. 26 at 3. Relator also contended the FCA's public-disclosure bar did not apply, as (1) certain documents were not publicly available and (2)

data published by CMS does not constitute a public disclosure as it would not have put the Government on notice of Dr. Odom's fraud, as Relator "applied his medical knowledge and experience to what the data revealed and to what it did *not* reveal." ECF No. 26 at 5. Even if there had been a public disclosure, Relator contended, he is an "'original source'—an individual 'who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.'" *Id.* at 7 (quoting 31 U.S.C. § 3730(e)(4)(B)(2)). Relator agreed Rule 9(b) applied to his FCA claims, but nonetheless contended the allegations in the Complaint satisfied the rule's particularity requirements by alleging the time, place, and contents of the misrepresentations, as well as a pattern of conduct that would necessarily have led to the submission of false claims to the Government for payment. *Id.* at 8-10. Finally, Relator opposed Dr. Odom's request for attorneys' fees and costs.

Dr. Odom replied, contending for the first time that he is not the proper party to this action, and Relator failed to join the proper parties, Hartsville Anesthesia Associates, P.A., and Advanced Pain Therapies, LLC. ECF No. 27 at 2. At a minimum, Dr. Odom argued, these entities are essential parties as all reimbursements would have been received by them and he was only their employee. Dr. Odom asserted Relator formulated medical opinions without the necessary experience, knowledge, or qualifications, and is "nothing more than a data miner." *Id.* at 3. Dr. Odom noted there are multiple obvious alternative explanations for his billing activity, including his participation in a clinical trial. Further, Dr. Odom disputed Relator is an original source and disputed the allegations in the Complaint meet Rule 9(b)'s particularity standard.

On September 14, 2020, Dr. Odom filed a supplemental motion to dismiss (Supplemental Motion to Dismiss) under Rule 12(b)(1) of the Federal Rules of Civil Procedure and the FCA's government-action bar, 31 U.S.C. § 3730(e)(3). ECF No. 38. According to Dr. Odom, application of the government-action bar required dismissal of Relator's complaint for lack of subject matter jurisdiction because the Complaint does not extend beyond the boundaries of two current administrative proceedings against him and numerous previous administrative proceedings against other health care providers. *Id.* at 4. Relator responded the government-action bar does not apply because none of the administrative proceedings relied upon by Dr. Odom constitute a civil suit or administrative penalty proceeding as required to trigger the government-action bar. ECF No. 39 at 1. Further, Relator contended, "[e]ven if the administrative materials relied upon by [Dr. Odom] did constitute a civil suit or penalty proceeding (which they do not), they are not based on the same allegations or transactions as in this case, and, therefore," the government-action bar "does not apply." *Id.* Dr. Odom replied the administrative proceedings currently pending against him constitute civil money penalty proceedings under the government-action bar, and the previous administrative proceedings against other health care providers support his position the nerve-conduction studies he performed as alleged in the Complaint were medically necessary. *Id.* at 1, 5. Dr. Odom also contended he was entitled to exhaust his administrative remedies prior to this court exercising jurisdiction over Relator's FCA claims. *Id.* at 6-8. Finally, Dr. Odom again sought attorneys' fees and costs.

For the reasons set forth by order of this court filed February 2, 2021, ECF No. 47, the court: (1) denied Dr. Odom's Initial Motion to Dismiss, ECF No. 18, with the exception of

Relator's FCA claims relating to CPT Code 76942 for years 2015, 2016, and 2017, which the court dismissed without prejudice; (2) denied in full Dr. Odom's Supplemental Motion to Dismiss, ECF No. 38; and (3) denied in full Dr. Odom's requests for attorneys' fees and costs. Additionally, because Dr. Odom did not file a motion to dismiss the Complaint under Rule 12(b)(7) of the Federal Rules of Civil Procedure for failure to join Hartsville Anesthesia Associates, P.A. and Advanced Pain Therapies, LLC as parties required to be joined under Rule 19 of the Federal Rules of Civil Procedure, the court took no action in response to Dr. Odom's unsupported argument that, at a minimum, these two entities are essential parties to this action. ECF No. 47 at 9 n.2.

Following the close of discovery, the parties filed cross motions for summary judgment, ECF Nos. 52, 53, and responses, ECF Nos. 54, 55. Additionally, Relator filed a reply to Dr. Odom's opposition to Relator's motion for summary judgment. ECF No. 56.

Relator's motion for summary judgment pertains solely to his FCA claims involving Claim-Sets One, Two, and Three, ECF No. 52 at 1 n.1, while Dr. Odom's motion for summary judgment seeks summary judgment *in toto*, ECF No. 53-1 at 8–26. Notably, in Relator's response in opposition to Dr. Odom's motion for summary judgment, Relator declares he does not oppose entry of summary judgment in Dr. Odom's favor with respect to Claim-Set 4. ECF No. 55 at 1 n.1.

IV. Summary Judgment Standard

The summary judgment standard is well-settled. Pursuant to Federal Rule of Civil Procedure 56, summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R.

Civ. P. 56(a). Thus, the movant shoulders to burden "to show the court that no material factual issues exist for trial." *Austin v. Clark Equipment Co.*, 48 F.3d 833, 835 (4th Cir. 1995). A genuine dispute as to a material fact exists if the evidence, viewed in the light most favorable to the nonmoving party and drawing all reasonable inferences in the nonmoving party's favor, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986), "is such that a reasonable jury could return a verdict for the nonmoving party," *id.* at 248. Under this standard, "the mere existence of a scintilla of evidence" in favor of the nonmovant's position is insufficient to withstand a properly supported motion for summary judgment. *Id.* at 252. The same is true of mere conclusory allegations or denials. *Wai Man Tom v. Hospitality Ventures LLC*, 980 F.3d 1027, 1037 (4th Cir. 2020).

Moreover, "although the court should review the record as a whole, it must disregard all evidence favorable to the moving party that a jury would not be required to believe." *Reeves v. Sanderson Plumbing Products*, 530 U.S. 133, 151 (2000). This means, "the court should give credence to the evidence favoring the nonmovant as well as that 'evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that the evidence comes from disinterested witnesses." *Id.* (quoting 9A C. Wright & A. Miller, *Federal Practice and Procedure* § 2529, p. 300 (2d ed. 1995)).

Next, [w]hen the moving party has carried its burden, the nonmoving party must come forward with evidence which shows more than some 'metaphysical doubt' that genuine and material factual issues exist." *Austin v. Clark Equipment Co.*, 48 F.3d 833, 836 (4th Cir. 1995) (quoting *Matsushita Elec. Indus. Co. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)). Notably, the nonmoving party may not circumvent summary judgment by presenting a mere scintilla of

evidence. *Id.* "Rather, the nonmoving party must convince the court that upon the record taken as a whole a rational trier of fact could find for the nonmoving party." *Id.*

V. Relevant Facts Undisputed by the Parties or Facts for Which the Record Does Not Support a Genuine Dispute of Material Fact

The following facts are not in dispute or the record does not support a genuine dispute of material fact. Dr. Odom is a Board-certified anesthesiologist. ECF Nos. 1 at 2, 49 at 2. At all times relevant to this case, he primarily practiced medicine in Irmo, South Carolina and was enrolled in and provided medical services to patients insured under Medicare Part B. *Id.* His Medicare NPI is 1598717167. *Id.* Additionally, the Medicare NPI registrations for both Hartsville Anesthesia Associates and Advanced Pain Therapies list Dr. Odom as President and Authorized Official for Information. https://npiregistry.cms.hhs.gov/registry/provider-view/1154539278 (Advanced Pain Therapies) (last viewed October 28, 2021); https://npiregistry.cms.hhs.gov/registry/provider-view/1871701029 (Hartsville Anesthesia Associates) (last viewed October).

For years 2016 and 2017, Dr. Odom was a principal investigator in an ongoing national clinical trial entitled "Physician Clinical Trial Policy (CPT) Neurological Ischemia Lower Extremity Pain and Swelling" with NCT number 01979367 ("NCT 01979367"). ECF No. 53-3 at 2; https://clinicaltrials.gov/ct2/show/NCT01979367 (last visited October 28, 2021). The trial's stated purpose was to evaluate the efficacy of "treatment of lower extremity pathologies derived from neurological ischemia disorders using the combination of Monochromatic Infrared Photo Energy (MIRE) and Transcutaneous Electrical Nerve Stimulation (TENS) therapies." ECF No.

54-8 at 2. The trial's official documents also refer to this treatment as "Small Pain Fiber Nerve Regeneration Therapy . . . ." ECF No. 54-8 at 7. In carrying out the trial, subjects are treated with MIRE therapy in specified amounts within seventy-two hours of previous treatments and undergo TENS therapy in specified amounts "at the subjective site for pain and each vertebrae nerve base, when impairment is confirmed" via a small pain fiber nerve conduction study, *id.* at 3, using the Neural Scan/Axon II device, *id.* at 4. Under the trial's protocol, treatments continue until objective diagnostic testing using the Neural Scan/Axon II device, "objectively indicate[s] affected small nerve fibers are functioning within normal range." *Id.* at 3. To help control nerve wake-up pain as nerves regenerate, the protocol provides: "Nerve block treatments may be utilized to control pain until such time as the above described therapies effectively replace the need for additional pain control measures." *Id.*; ECF No. 53-7 at 2–3. Dr. Odom claims he always used the Axon-II device to perform the small pain fiber nerve-conduction studies on his patients enrolled in NCT 01979367. ECF No. 53-1 at 11. In doing so, he never also performed electromyography.[2]

At all times relevant to the instant case, Palmetto Government Benefit Administrators, LLC ("Palmetto GBA") served as the MAC for the geographic jurisdiction in which Dr. Odom practiced medicine. Notably, Palmetto GBA issued LCD 35048 approximately three months prior to Dr. Odom submitting his first claim under 95909 in 2016. ECF No. 52-9 at 2. LCD 35048 prohibits Medicare reimbursement for nerve-conduction studies in the absence of concurrent

[2] Electromyography "is the study and recording of intrinsic electrical properties of skeletal muscles," and "is carried out with a needle electrode." ECF No. 52-9 at 5.

electromyography testing, except in the case of carpal tunnel syndrome. ECF Nos. 52-8 at 2, 10, 52-9 at 4–5, 8. LCD 35048 cites the Axon II as an example of a device that does not meet the requirement for separate payment under Medicare Part B for its use. ECF No. 52-8 at 11. In 2020, ALJ Keith W. Sickendick (ALJ Sickendick) rejected a challenge to this portion of LCD 35048 (and identical portions of other LCDs) on the basis "the LCD records are complete and adequate to support the validity of the LCDs at issue in this case." ECF No. 52-8 at 2. The record indicates the aggrieved parties have appealed ALJ Sickendick's decision to the Medicare Appeals Council where it remains pending. ECF Nos. 54 at 7, 54-3.

Palmetto GBA initially paid all the claims Dr. Odom submitted under CPT Code 64450 and under his Medicare NPI for services he performed in 2016 on 94 patients, a total of $476,715. ECF Nos. 1 at 10, 13–14, 41-1 at 3; 52-3 at 2–7, 52-4 at 2–5; 55-2 at 2–3. Subsequently, on September 19, 2017, Palmetto GBA sent a letter to Dr. Odom's attention at the address of Hartsville Anesthesia Associates requesting medical records needed to conduct a post-payment review for dates of service January 1, through December 31, 2016. ECF No. 52-3 at 2. The request was prompted by (1) the national paid-claims error-rate for claims submitted to Medicare Part B under CPT 64450 and (2) the fact analysis of the sheer quantity of services Dr. Odom, in conjunction with Hartsville Anesthesia Associates, billed Medicare Part B under CPT Code 64450 for services Dr. Odom performed in 2016 indicated the possibility of inappropriate billing. ECF Nos. 41-1 at 3, 52-3 at 2. Accordingly, Palmetto GBA conducted a post-payment review of a 486-claim sample involving the medical records of 30 of the 94 patients for whom Dr. Odom had submitted claims under Code 64450 for services he performed in 2016. ECF Nos. 41-1 at 3, 52-3

at 2. Using that sample of claims, Palmetto GBA "found an error rate/denial rate of 100%," ECF No. 41-1 at 3, resulting in Palmetto GBA determining by extrapolation it had overpaid Dr. Odom $445,825.05, for the following primary reasons: (1) the documentation submitted did not meet medical necessity requirements per CMS guidelines; (2) the documentation submitted was altered; (3) the documentation submitted was for the wrong patient, the wrong date of service, or was the wrong documentation; (4) no documentation was received as requested; or (5) the claim was billed in error. ECF Nos. 41-1 at 3; 52-4 at 2–5; 52-5 at 2.

Dr. Odom requested a redetermination of this claw-back decision on the basis he was a principal investigator of NCT 01979367, all claims at issue in the 486-claim review sample were furnished for patients in such clinical trial, and Medicare "appeal decisions have already established that by National Library of Medicine issuance of the NCT #01979367 and a princip[al] investigator[']s submittal of a claim, [such clinical trial] is a qualifying Clinical Trial Study with certified Physicians and[/]or Practitioners as princip[al] investigators at every location."[3] ECF No. 52-6 at 4–5. Upon redetermination, Palmetto GBA upheld its prior decision but did not specifically address Dr. Odom's Clinical Trial Defense. ECF No. 41-1 at 11; 52-6 at 4–5. Rather, Palmetto GBA's primary reason for upholding its decision at the redetermination stage included the following: "Peripheral nerve blocks or injections for the treatment of diabetic peripheral neuropathy (chronic pain) are not covered. At this time, there is insufficient literature/scientific

[3] For ease of reference, at times, the court will refer to this explanation by Dr. Odom as his "Clinical Trial Defense."

evidence to support the use of peripheral nerve blocks or injections for peripheral neuropathies caused by underlying systemic diseases." ECF No. 41-1 at 11.

Continuing to challenge Palmetto GBA's adverse decision, in a letter dated April 11, 2018, Dr. Odom sought a QIC review, raising six arguments in his defense. ECF No. 52-7 at 2–6. Medicare in turn contracted with C2C Innovative Solutions, Inc. (C2C) to conduct the requested QIC review. ECF No. 41-1 at 2. As relevant here, Dr. Odom raised his Clinical Trial Defense and contended Palmetto GBA erred by failing to address it. ECF No. 41-1 at 10–11, 52-7 at 3.

Additionally, Dr. Odom asserted in his defense that C2C, acting as a QIC, "has had the opportunity to rule on the validity of the same clinical trial, including various services rendered thereunder, on several occasions in the past," and upheld "the clinical trial policy, as well as individual services rendered thereunder." ECF No. 52-7 at 3. In support, Dr. Odom listed three QIC decisions by Medicare Appeal Number involving different Medicare providers or suppliers. *Id.* at 4. All patient, provider, and/or supplier names are redacted in the copies filed with the court in the instant case. The first and the third decisions contain information revealing C2C rendered the QIC decision, but the second decision does not.

In the first QIC decision listed by Dr. Odom, C2C determined payment can be allowed under CPT Code 95909 for five or six nerve conduction studies performed on each of three days in the last quarter of 2015 (September 25, 2015, September 28, 2015, and November 27, 2015), representing three separate claims. ECF No. 27-4. This first decision, issued May 20, 2016, nowhere mentions NCT #01979367. *Id.* Rather, C2C allowed the claims because: (1) nerve conduction studies are standard procedures in the study of peripheral nerve disease in that "[t]he

measurement of nerve conduction is useful as a diagnostic tool to distinguish major categories of disease (axonal vs. demyelinating) and can localize entrapments and other mononeuropathies, *id.* at 3, 6, (2) for one of the claims, the medical record contained a physician's progress note documenting the patient's complaints of numbness, tingling, and allodynia in the toes, feet, and ankles, documented the patient rated her pain nine out of ten in both feet, *id.* at 4, (3) for the other two claims the medical records documented the patient's diagnosis of ischemia and noted the patient's complaint of pain, numbness and tingling, *id.* at 7, and (4) for all three claims, the documentation was signed by the provider and the medical records contained the results of the nerve conduction studies, *id.* at 4, 7.

The identity of the QIC in the second decision is completely redacted. In such decision, the QIC determined payment can be allowed under CPT Code 95909 for five or six nerve conduction studies performed on July 26, 2016. ECF No. 27-5. Unlike the first QIC decision, this one discusses NCT #01979367. *Id.* at 5. Initially, the applicable MAC had denied the claim on the basis "the clinical trial was not registered with Medicare" and "the submitted documentation was insufficient to establish medical necessity." *Id.* At the QIC level, the QIC approved the claim on the basis (1) "the submitted documentation now includes evidence that this beneficiary is enrolled in . . . NCT # 01979367, which is an approved clinical study registered with Medicare," and (2) "the documentation on file reflects the physician's recommendation for the nerve conduction studies trial due to the beneficiary's ongoing complaints of lower extremity pain related to peripheral vascular disease." *Id.*

The third QIC decision submitted by Dr. Odom reviewed the applicable MAC's denial of payment for a claim under CPT Code 95909 for five or six nerve conduction studies performed on June 30, 2016. ECF No. 27-6. A cover letter for the decision reveals C2C was the QIC. *Id.* at 3. Much of the language, and ergo the reasoning, in the "Explanation of the Decision" portion of the third QIC decision is identical to the second one just discussed, including the finding "NCT # 01979367 . . . is an approved clinical trial registered with Medicare." *Id.* at 5. The only relevant differences are the date of service of the five or six nerve conduction studies and the third decision does not identify peripheral vascular disease as the cause of the patient's lower extremity pain. *Id.*

As a separate argument, but one still in support of his Clinical Trial Defense, Dr. Odom argued his claims should be covered because "[t]he Clinical Trial Policy has also been determined at the [ALJ] level to be a valid Clinical Trial Policy and the services rendered herein to be reimbursable." ECF No. 52-7 at 4. In support of this argument, Dr. Odom cited and included as an exhibit a copy of a decision dated April 13, 2016, by ALJ Marilyn Mann Faulkner (ALJ Faulkner) of the Office of Medicare Hearings and Appeals, Western Field Office, Irvine, California, in a case wholly unrelated to Palmetto GBA's claw-back decision adverse to Dr. Odom. ECF No. 54-10. A copy of ALJ Faulkner's decision is in the summary judgment record with all personally identifying information redacted. *Id.* The primary issue in that case was whether NCT # 01979367 is a qualifying clinical trial under Medicare, such that the provider's claims for Medicare coverage of routine costs associated with the trial were covered under Medicare. *Id.* at 2. Both the MAC and the QIC had denied the claims on the basis "the [p]rovider failed to enroll its medical study entitled Neurological Ischemia – Lower Extremity Pain and Swelling –

(registration number NCT01979367) in the Medicare clinical trials registry." *Id.* at 1. Upon ALJ Faulkner first receiving the case, she remanded it "to the QIC because it appeared that the medical study [at issue] was in fact registered in the Medicare clinical trials registry." *Id.* In response to the remand order, the QIC issued a new reconsideration decision stating in relevant part: "'The webpage referenced in the order, www.ClinicalTrials.gov, is the official site used by [the QIC] to validate clinical trials. The study in question, Study of Neurological Ischemia Lower Extremity Pain and Swelling (NCT01979367) is listed on the website with a start date of March 2012.'" *Id.*

In the decision, ALJ Faulkner correctly quotes the requirement in NCD 310.1 providing "'[c]linical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria.'" *Id.* at 5 (quoting NCD 310.1). In the next sentence, ALJ Faulkner correctly quotes NCD 310.1 as providing "'[t]his process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.'" *Id.* (quoting NCD 310.1). As part of her analysis, ALJ Faulkner found the administrative record substantiated testimony given in the case that NCT 01979367 "was in fact registered in the Medicare clinical trials registry." *Id.* at 7. In this regard, ALJ Faulkner explained:

> The Provider submitted a page from www.ClinicalTrials.gov, which shows that the clinical trial was registered with Medicare at www.ClinicalTrials.gov. Indeed, the QIC's November 10, 2015 reconsideration decision (sent in response to my Order of Remand) explicitly states: "The webpage referenced in the order, www.ClinicalTrials.gov, is the official site used by the [QIC] to validate clinical trials. [NCT 01979367] is listed on the website with a start date of March 2012." Therefore, the QIC erred when it denied the Provider's Medicare claim for failing to register the medical study at issue in the Medicare clinical trials registry.

> With respect to the issue of routine costs, in this case, it appears that the costs submitted were in fact routine costs associated with the qualifying clinical trial and involved services approved by the FDA for ischemic disorders and pain. Such costs include infrared treatment, small pain fiber testing, injections of anesthetics, TENS unit, training for using the TENS unit at home, face-to-face evaluations, and patient questionnaires. All costs are routinely incurred to provide services or items used for the diagnosis of, treatment of, or prevention of complications from neurological ischemic disorders resulting in lower extremity pain and swelling. Routine costs also are items or services that are typically provided and required for the clinical investigation and are clinically appropriate to monitor the effects of the item or service for the diagnosis, treatment or prevention of complications.

Id. at 7–8 (first alteration in original). Based upon this analysis, ALJ Faulkner concluded, the "[n]umerous procedure codes billed by the Provider on numerous dates of service are eligible for Medicare coverage as routine costs of a qualifying clinical trial . . . ." *Id.* at 8.

Dr. Odom's remaining arguments mainly focused on his position the claims should be covered because they were not investigational, but reasonable and medically necessary. ECF 41-1 at 12-13. In a letter dated August 30, 2018, Dr. Odom was notified the QIC "decision is UNFAVORABLE," ECF No. 41-1 at 2. C2C did not accept any of Dr. Odom's arguments, *id.*, and in response to his complaint Palmetto GBA failed to address his Clinical Trial Defense, C2C stated its *de novo* reconsideration would cure the failure and further stated:

> While the services may have been rendered under a clinical trial, that alone does not determine coverage. The QIC reviews all services against Medicare rules and regulations, as well as accepted standards of medical practice. Therefore, the enrollment in a clinical trial alone does not automatically ensure services are covered.

ECF No. 41-1 at 11.

In response to Dr. Odom's Clinical Trial Defense, C2C stated: "ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine. It is a registry site for clinical trials;

however, listing a study does not mean it has been evaluated by the U.S. Federal Government. Appellant has provided no evidence demonstrating Medicare approval of this study." *Id.* at 11. Although C2C did not directly address the prior QIC decisions cited by Dr. Odom, it eschewed ALJ Faulkner's decision as nonbinding. *Id.* at 12. In the "Claim Review" portion of its QIC Decision, C2C denied 100 claims for altered documentation, 10 for medical records sent for the wrong patient, wrong date of service, or lack of documentation, 40 for the wrong documentation, and 48 billed in error. *Id.* at 14. C2C denied the remaining claims as not medically necessary. *Id.* at 15. In conclusion, C2C found an overpayment was made because the services did not meet the Medicare requirements to be considered reasonable and necessary in the treatment of patients. *Id.*

According to Odom, he noted a timely appeal of this decision (the QIC Decision), which is currently pending (*i.e.*, awaiting a hearing date before an ALJ). ECF Nos. 38 at 4, 40 at 4. Dr. Odom retired from the practice of medicine in 2018 due to a medical disability caused by heavy metal contaminated ground water. ECF No. 53-3 at 1.

The summary judgment record does not contain an electronic version or a paper copy of a single CMS-1500 claim form at issue. Relator offers no explanation for this circumstance despite the fact he brought the instant action on behalf of the Government who presumably would be in possession of such material. For his part, in Dr. Odom's responses to Relator's Second Set of Interrogatories, Dr. Odom represented he does not have copies of the billing records for any of the Claim-Sets at issue in the Complaint. ECF No. 52-2 at 3. In explanation, Dr. Odom states a third-party biller, *i.e.*, Medical Management Services, Inc., performed all such billing and "retained these records for Defendant, but does not retain their records after one year." *Id.*

Also, the summary judgment record does not contain a single medical record. This is so despite, as part of discovery in this case, Dr. Odom electronically transmitted thirty of the medical records at issue to Relator and made the remainder available to Relator or anyone assigned to Relator for inspection in a single warehouse in Hartsville, South Carolina. ECF No. 53-3 at 3 (Affidavit of Dr. Odom).

VI. Claim-Sets One and Two

A. Relator's Motion for Summary Judgment

The court first takes up Relator's motion for summary judgment on his claims Dr. Odom violated subsections (a)(1)(A) and/or (a)(1)(B) of 31 U.S.C. § 3729 by: (1) presenting 14,541 claims for payment under CPT Code 64450 for nerve-block injections he performed on 94 patients, averaging 155 injections per patient, in 2016, for which the Government paid him a total of $476,715, *i.e.*, Claim-Set One; and (2) presenting 12,749 claims for payment under CPT Code 64450 for nerve-block injections he performed on 110 patients, averaging 116 injections per patient, in 2017, for which the Government paid him $411,321, *i.e.*, Claim-Set Two. After some evolving theories of FCA liability on Relator's part as to Claim-Sets One and Two, Relator has settled on two alternative theories of liability. In the first, Relator alleges Dr. Odom submitted Claim-Sets One and Two for nerve-block injections he did not perform, but instead performed small-pain-fiber nerve-conduction studies using the Axon-II device. ECF No. 56 at 5–7. Relator bases this theory upon Dr. Odom's repeated assertions during this litigation he performed all nerve injections identified in the Complaint pursuant to protocol in and as a principal investigator of NCT 01979367. ECF No. 56 at 5–6. Alternatively, Relator alleges, "[e]ven assuming *in arguendo*,

that Dr. Odom actually gave anesthetic injections in connection with all of the claims he submitted under CPT Code 64450, such claims are false and fraudulent because he performed a grossly excessive number of injections per patient per year." *Id.* at 7. This alternative theory is based in part upon Dr. Odom's assertion in his response to Relator's Motion for Summary Judgment that "[t]he record unequivocally states Dr. Odom was utilizing these nerve block injections to treat the pain which occurs when a patient's ischemia begins to improve," as the result of a patient's treatment as a participant in NCT 01979367. ECF No. 54 at 6–7. *See also* ECF No. 49 at 13 (Dr. Odom asserting the following as part of his Fourth Affirmative Defense (Good Faith): "All nerve injections identified in Plaintiff-Relator's Complaint were part of the approved protocol and were performed during [NCT 01979367].").

The court rejects as untenable Relator's first theory of liability alleging Dr. Odom submitted Claim-Sets One and Two for nerve-block injections he never performed, but instead performed small-pain-fiber nerve-conduction studies using the Axon-II device. The theory is untenable for two reasons. First, the theory hinges upon an overreading of Dr. Odom's explanation as to why he submitted Claim-Sets One and Two. When Dr. Odom stated he performed all nerve-block injections identified in the Complaint pursuant to NCT 01979367 protocol and as one of its principal investigators, he plainly meant nothing more than he performed the nerve-block injections in keeping with NCT 01979367's protocol providing: "Nerve block treatments may be utilized to control pain until such time as the above described therapies effectively replace the need for additional pain control measures." ECF No. 54-8. The second reason Relator's first theory is untenable is the record does not contain any evidence supporting it. For example, the record does

not contain a single copy of a CMS-1500 claim form submitted by Dr. Odom as part of Claim-Sets One and Two nor a corresponding medical record (with patient identifying information redacted except for initials) showing the same patient underwent small-pain-fiber nerve-conduction studies on the same date. While Relator puts all the blame for the lack of an electronic version or a paper copy of a CMS-1500 claim form at issue on Dr. Odom, Relator offers no explanation as to why he did not obtain this evidence from the Government on whose behalf he has brought this action. Moreover, despite Relator's ability to inspect the medical records of Dr. Odom's patients who are the subjects of Claim-Sets One and Two, Relator offers no evidence of the content of such medical records in support of his first theory.

Moving on to Relator's alternative theory, the court assumes *arguendo* Relator meets his burden on the common elements of causation and materiality in subsections (a)(1)(A) and (a)(1)(B) and the element of presentment in subsection (a)(1)(A). Even so, Relator's motion for summary judgment on Claim-Sets One and Two runs into trouble on the common elements of falsity and scienter and the element of a false record or statement in subsection (a)(1)(B). Denial of Relator's motion for summary judgment as to Claim-Sets One and Two is compelled by the existence of a genuine issue of material fact as to these three elements.

On the common element of falsity and the element of a false record or statement in subsection (a)(1)(B), Relator submits Dr. Odom falsely claimed Medicare Part B covered the nerve-block injections that were the subject of those claims and/or made a false record or statement in connection therewith. In support, Relator cites three items.

First is Dr. Odom's volume of claims. The annual nationwide mean per patient for nerve-block injections claimed under CPT Code 64450 is 2.38 compared to Dr. Odom's average of 155 in 2016 and 116 in 2017. ECF Nos. 1 at 10, 55-2 at 2–3. Additionally, for 2017, Dr. Odom submitted more claims for CPT Code 64450 than any other physician in the United States. *Id.*

Second is an expert opinion by Jeff Gelblum, MD (Dr. Gelblum), a board-certified neurologist, to the effect the vast quantity of anesthetic nerve-block injections performed on each patient as represented in Claim-Sets One and Two exceeded the reasonable realm of accepted clinical practice regardless of the diagnosis. ECF No. 55-1 at 7.

The court must digress here for a moment to explain why Dr. Odom's challenge to a particular portion of Dr. Gelblum's expert witness report does not come into play here. At the time Dr. Gelblum prepared his expert witness report, he had twenty-nine years of experience in the clinical practice of neurology. ECF No. 55-1 at 3. He maintains staff privileges at a level II Trauma Center, is an Assistant Clinical Professor of Neurology at the Nova Southeast College of Medicine and utilizes ultrasound guidance and injections in the treatment of neurologic disease. *Id.* Dr. Odom does not take issue with Dr. Gelblum's credentials, experience, and expertise to offer his expert opinion on issues of the treatment of neurological diseases and disorders in general. Rather, Dr. Odom takes issue with Dr. Gelblum's opinion that, based upon Dr. Odom's training and experience, Dr. Odom knew or should have known the nerve-block injections at issue in Claim-Sets One and Two were medically unreasonable and unnecessary, because, in forming such opinion, Dr. Gelblum erroneously inferred Dr. Odom performed the injections to treat pain related to peripheral neuropathy. *E.g.*, ECF No. 53-1 at 15. According to Dr. Odom, if Dr. Gelblum had

bothered to review at least one patient medical record, all of which Dr. Odom represents he made available to Relator in discovery, Dr. Gelblum would have discovered Dr. Odom was treating patients enrolled in NCT 0197367 for lower extremity ischemia and not for peripheral neuropathy. *Id.* Dr. Odom's point is moot for purposes of the court's present analysis because the court does not rely upon Dr. Gelblum's expert opinion inferring Dr. Odom was treating peripheral neuropathy. Rather, the court only relies upon Dr. Gelblum's opinion to the effect the quantity of anesthetic nerve-block injections performed on each patient as represented in Claim-Sets One and Two exceeded the reasonable realm of accepted clinical practice regardless of the diagnosis.

The third item evidencing falsity and false records is the QIC Decision in which C2C upheld clawing-back the extrapolated overpayment to Dr. Odom of $445,825.05 as to his 2016 claims under CPT Code 64450 despite Dr. Odom asserting his Clinical Trial Defense. ECF No. 41-1 at 2–503. C2C rejected the defense for lack of evidence NCT 0197367 is a Medicare qualifying clinical trial. Moreover, in the "Claim Review" portion of its decision, C2C denied 100 claims for altered documentation, 10 for medical records sent for the wrong patient, wrong date of service, or lack of documentation, 40 for the wrong documentation, and 48 billed in error. ECF No. 41-1 at 14. C2C denied the remaining claims as not medically necessary. *Id.* at 15.

Although these three items of evidence might get Relator to a jury on the issue of whether, in submitting Claim-Sets One and Two for payment under Medicare Part B, Dr. Odom falsely claimed Medicare Part B covered the nerve-block injections and/or made a false record or statement, Dr. Odom has forecast sufficient evidence to create a genuine issue of material fact on this issue.

Dr. Odom has submitted his own affidavit attesting he was a principal investigator in NCT 0197367, and, pursuant to the trial protocol, "[p]atients who experience 'wake-up' pain associated with the progress of increasing circulation and restoring function receive nerve blocks at the five major nerves of the ankle." ECF No. 53-3 at 2. He has also submitted the affidavit of Dr. Michael Boyer (Dr. Boyer), a board-certified anesthesiologist who is a trainer for the sponsors and managers of NCT 0197367. ECF No. 53-7 at 1. According to Dr. Boyer's affidavit, after reviewing a sampling of 30 patient charts of Dr. Odom's patients who were enrolled in NCT 0197367, Dr. Odom's choice and frequency of nerve-block injections to treat wake-up pain when pain from ischemia begins to improve was medically reasonable and necessary and not performed in excess. ECF No. 53-7 at 1–2. Buttressing this conclusion, Dr. Boyer opined:

> The thirty charts in question were voluminous and detailed. It is clear from this review that Dr. Odom has gone to great efforts in developing forms and protocols to meet the detailed criteria of the study. The records are coherent and provide substance and clear indication of purpose in close evaluation regarding patient progress and medical necessity for the treatments.

Id. at 2. Notably, Relator does not make a *Daubert*-type challenge to Dr. Boyer's opinions.[4]

Dr. Odom also submitted the affidavit of Dr. Chad Pfefer, M.D., (Dr. Pfefer), a board-certified internist, who has practiced medicine for more than twenty-years and who is study chair and principal investigator of NCT 0197367. ECF No. 53-6 at 1. Dr. Pfefer helped create the

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[4] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993) (holding scientific evidence is admissible under Federal Rule of Evidence 702 if "it rests on a reliable foundation and is relevant")

procedures and protocols for NCT 0197367, which has as its purpose to further medical knowledge regarding the diagnosis and treatment of patients with chronic lower extremity pain. *Id.* at 2. Dr. Pfefer also reviewed a sampling of 30 patient charts of Dr. Odom's patients who were enrolled in NCT 0197367. After review, Dr. Pfefer opined Dr. Odom was treating the patients for an underlying painful ischemic disorder, not for peripheral neuropathy, the treatment was provided in accordance with NCT 's 0197367 protocols and procedures, and "Dr. Odom's medical records reflect that his care and treatment of the patients was within the prevailing medical standard of care and treatment." ECF No. 53-6 at 2–3. Relator does not make a *Daubert*-type challenge to Dr. Pfefer's opinions.

Finally is the affidavit of Sean Weiss, a purported expert in the field of health care regulatory compliance, with twenty-five years of experience and expertise in medically billing, coding, and documentation. ECF No. 53-5 at 2–7. Of particular relevance on the falsity/false record issue, Sean Weiss offered the following expert opinion:

> Dr. William Odom was involved in a Nation[al] Clinical Trial in the years 2016 and 2017. I have personally reviewed thirty medical records of patients of Dr. Odom during this time period. All thirty patients were enrolled in . . . NCT 01979367.
>
> None of the medical records reviewed contained a diagnosis of peripheral neuropathy.
>
> The National Clinical Trial is properly registered at clinicaltrials.gov and complies with CMS guidelines.
>
> I have personally reviewed the protocol for [NCT 01979367] and found Dr. Odom's treatment of . . . all the patients as reflected in the medical records met the requirements of [NCT 01979367] and CMS regulations and guidelines. More specifically, those set forth in the Medicare Program Integrity Manual (PIM). The

> definition of medical necessity as utilized by CMS was met in that Dr. Odom exercised his prudent clinical judgment and provided the services in a clinically appropriate fashion including, frequency and extent. Dr. Odom's medical records were clear, concise, and more than adequate to meet all requirements of CMS.

ECF No. 53-5 at 7 (paragraph numbering omitted).

The bottom line with respect to the element of falsity and/or false records is, viewing the evidence in the record in the light most favorable to Dr. Odom as the non-moving party, Dr. Odom has carried his burden of forecasting sufficient evidence to create a genuine issue of material fact. Although Relator has submitted evidence Claim-Sets One and Two falsely represent the nerve-block injections are medically necessary, Dr. Odom has submitted evidence the same nerve-block injections are either medically necessary or payable as routine costs of a Medicare qualifying clinical trial.

Turning to the element of scienter, Relator's initial burden is to show Dr. Odom submitted Claim-Sets One and Two for payment and/or made a statement leading to such submissions with at least reckless disregard for the truth or falsity of his claims or statements that the nerve-block injections were covered by Medicare Part B. Relator has carried this burden. First, as a participant in the Medicare program, Dr. Odom had a duty to familiarize himself with the legal requirements for Medicare Part B coverage of the nerve-block injections he administered pursuant to NCT 01979367. *Heckler*, 467 U.S. at 64. In other words, Dr. Odom could not just bury his head in the sand regarding Medicare Part B coverage and fail to make an inquiry into the validity of such a claim that would be reasonable and prudent under the circumstances. *United States ex rel. Int'l Brotherhood of Elec. Workers Loc. Union No. 98 v. Fairfield Co.*, 5 F.4th 315, 348 (3d Cir. 2021)

("Congress added the 'reckless disregard' prong to the FCA's definition of 'knowingly' to target the defendant who has buried his head in the sand and failed to make an inquiry into the claim's validity that is reasonable and prudent under the circumstances.") (some internal quotation marks omitted). Second, the evidence the court has already recounted on the element of falsity, *see supra* pp. 32–34, is also probative on the issue of scienter. Third, Palmetto GBA and C2C acting as the QIC both concluded Dr. Odom had submitted claims in Claim Set One with altered documentation, which shows his consciousness of guilt. Added to this, Relator has submitted a copy of a document entitled "Advance Beneficiary Notice (ABN) And Contract for Service." ECF 55-3 at 2. Dr. Odom is listed as the "Physician" and Advanced Pain Therapies, LLC is listed for "Group Name." *Id.* The name of the patient, the patient's signature, and other identifying information about the patient are redacted. The patient dated the document June 17, 2016. *Id.* As relevant here, the document notifies the patient Medicare or the patient's insurance may not pay for "*Pain Management/*Electrical Stimulation (TENS)/*Monochromatic Infrared Photo Energy (MIRE) Applications." *Id.* The asterisk refers to the following text at the bottom of the page: "Services are on the CMS physician/carrier fee schedule as normally payable events, when performed in a study." *Id.* Relator asserts without pointing to any evidentiary support that Dr. Odom provided this notice to all of his patients enrolled in NCT 01979367. ECF No. 55 at 14. While this assertion cannot be considered on summary judgment without underlying evidentiary support, the document is relevant on the issue of scienter to the extent it shows Dr. Odom had reservations about whether the nerve-block injections administered as part of NCT 01979367, *i.e.*, the "Pain Management" part of the trial, were covered by Medicare Part B.

In light of Dr. Odom's duty to familiarize himself with the legal requirements of billing Medicare under CPT Code 64450 for nerve-block injections he gave patients as part of their enrollment in NCT 01979367 and, the just outlined evidence, when considered *in toto* and in the light most favorable to Relator, the court concludes a reasonable finder of fact could find in favor of Relator on the issue of scienter. However, the evidence Dr. Odom has proffered on the issue of falsity is sufficient to create a genuine issue of material fact on the issue of scienter.

In summary, Relator is not entitled to summary judgment in his favor on Claim-Sets One and Two.

B. Dr. Odom's Motion for Summary Judgment

The court next takes up Dr. Odom's motion for summary judgment on Claim-Sets One and Two. Dr. Odom first argues he is entitled to summary judgment because the CMS data underlying these claim sets cannot be authenticated. Alternatively, Dr. Odom raises his Clinical Trial Defense. Neither entitles him to summary judgment on Claim-Sets One and Two.

As proof Dr. Odom submitted Claim-Sets One and Two, Relator relies upon publicly available data, published by CMS on its website CMS.gov, reporting exactly this information. ECF No. 52 at 3–4; *Medicare Provider Utilization and Payment Data: Physician and Other Supplier*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-trends-and-reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier (date last visited October 28, 2021); *Medicare Physician & Other Practitioners – by Provider and Service*, https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-provider-and-service/data/2016 (last

visited October 28, 2021). For his part, Dr. Odom does not dispute the Complaint accurately reports the publicly available data on CMS.gov for Claim-Sets One and Two. ECF No. 49 at 6. He also admits in his Answer that for the years 2016 and 2017, he averaged 155 claims and 116 claims under CPT Code 64450 per patient respectively.[5] *Id.* Notwithstanding these admissions, Dr. Odom attempts to cast doubt on the accuracy of the publicly available CMS data for Claim-Sets One and Two via the opinion of his proffered expert in the field of medical billing and coding that publicly available CMS billing information "has been show[n] to contain flaws, skewed utilization numbers and often do[es] not reflect actual payments made to providers of medical care," ECF No. 53-5 at 6 (Affidavit of Sean Weiss). Finally, Dr. Odom denies he, as an individual physician, ever submitted claims for reimbursement to Medicare. ECF No. 53-3 at 3 (Affidavit of Dr. Odom). Rather, he states any claims for medical services he provided were assigned to Hartsville Anesthesia or Advanced Pain Therapies, LLC and billed by those entities. *Id.*

The court rejects Dr. Odom's argument he is entitled to summary judgment on Claim Sets One and Two because the CMS data relied upon by Relator in support of those claims cannot be authenticated. Much of the CMS data relied upon by Relator in support of Claim-Sets One and Two is admitted by Dr. Odom in his Answer, and he has not forecast sufficient evidence, viewed

[5] The summary judgment record does not contain a copy of a single Medicare claim at issue nor billing records in support of such claim submissions. ECF No. 52-2 at 3. According to Dr. Odom, this is because a third-party biller performed all of his Medicare claim submissions and retained the records of such submissions for only one year. *Id.*

in the light most favorable to Relator, to require a reasonable jury to find the balance of such published information by a Government agency incorrect.

Dr. Odom's Clinical Trial Defense does not support summary judgment for two reasons. First, because Dr. Odom, a principal investigator in NCT 01979367, followed trial protocol in performing nerve-block injections to treat "wake-up pain" resulting from improving ischemia did not *ipso facto* turn Claim Sets One and Two into covered claims under Medicare Part B. This is because Medicare only "covers the routine costs of **qualifying** clinical trials . . . ." ECF No. 56-1 at 4. The second reason is the evidence in the record, viewed in the light most favorable to Relator, shows the existence of a genuine issue of material fact regarding whether NCT 01979367 is a qualifying Medicare trial as required by NCD 310.1 such that the nerve-block injections were covered as routine costs of a clinical trial. For example, C2C acting as a QIC rejected Dr. Odom's Clinical Trial Defense as to Claim Set One on the grounds registering a clinical trial at ClinicalTrials.gov does not mean it has been evaluated by the Government, and Dr. Odom "provided no evidence demonstrating Medicare approval of [NCT 01979367]." ECF No. 41-1 at 12. Moreover, the webpage for any particular clinical trial in ClinicalTrials.gov's clinical trial registry displays the following disclaimer: "The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government." *See*, *e.g.*, https://clinicaltrials.gov/ct2/show/NCT01979367?term=NCT+01979367&draw=2&rank=1 (last visited October 28, 2021). Furthermore, in none of the expert witness affidavits submitted by Dr. Odom does anyone expressly state or opine NCT 01979367 is a qualifying trial under Medicare;

"properly registered" yes, ECF No. 53-5 at 7 (Affidavit of Sean Weiss), "qualifying" no. "Properly registered" and "qualifying" could mean two different things depending on the scope of the phrase "properly registered." Finally, Dr. Odom has not offered any documentation establishing the lead principal investigator of NCT 01979367 certified it met the ten criteria necessary to constitute a qualifying clinical trial under Medicare as provided in NCD 310.1.

In sum, Dr. Odom is not entitled to summary judgment on Claim-Sets One and Two.

VII. Claim-Set Three

A. Relator's Motion for Summary Judgment

For Claim-Set Three, Relator seeks summary judgment on his claims Dr. Odom violated subsections (a)(1)(A) and/or (a)(1)(B) of 31 U.S.C. § 3729 by presenting 624 claims for payment under CPT Code 95909 and his Medicare NPI for a set of five or six nerve-conduction studies he performed in 2016 on 105 patients, averaging six sets of nerve-conduction studies per patient, for which the Government paid him $67,211. ECF No. 1 at 14. According to Relator, Dr. Odom knew or should have known Medicare does not cover these studies as they were not medically necessary, expressly excluded from coverage by an applicable LCD, and not performed pursuant to a qualifying Medicare clinical trial.

The court assumes *arguendo* Relator meets his burden on the common elements of causation and materiality in subsections (a)(1)(A) and (a)(1)(B) and the element of presentment in subsection (a)(1)(A). Nonetheless, Relator's motion for summary judgment on Claim-Set Three falters on the common elements of falsity and scienter and the element of a false record or

statement in subsection (a)(1)(B). Denial of Relator's motion for summary judgment on Claim-Set Three is compelled by the existence of a genuine issue of material fact as to these three elements.

On the common element of falsity and the element of a false record or statement in subsection (a)(1)(B), Relator submits Dr. Odom falsely claimed Medicare Part B covered the nerve conduction studies at issue and/or made a false record or statement in connection therewith. In support, Relator proffers evidence of the following: (1) Dr. Odom was the second highest biller in the nation in 2016 for Medicare claims submitted under CPT Code 95909, ECF Nos. 1 at 14, 55-2 at 1–3; (2) for 2017, nearly all other physicians who submitted claims under CPT Code 95909 did so only once per patient, *id.*; (3) LCD 35048, issued by Palmetto GBA on October 10, 2015, prohibited Medicare reimbursement for nerve conduction studies in the absence of concurrent electromyography testing, except in the case of carpal tunnel syndrome, ECF Nos. 52-8 at 10; 52-9; (4) an on-point ALJ decision considered and denied a challenge to LCD 35048's provision nerve-conduction studies using the Axon II are not separately payable under Medicare Part B, ECF No. 52-8 at 5, 10–12, 19; and (5) although Dr. Odom raises his Clinical Trial Defense here, as he did before Palmetto GBA and the QIC, the record lacks direct evidence the lead principal investigator of NCT 01979367 certified the study met the ten criteria necessary to constitute a qualifying clinical trial under Medicare as provided in NCD 310.1.

While this evidence might be sufficient for Relator to get to a jury on the issue of whether, in submitting Claim-Set Three for payment under Medicare Part B, Dr. Odom falsely claimed Medicare Part B covered the nerve-conduction studies and/or made a false record or statement, Dr. Odom has forecast sufficient evidence to create a genuine issue of material fact. Viewing the

evidence in the light most favorable to Dr. Odom, a genuine issue of material fact exists whether the claims in Claim-Set Three are payable under Medicare Part B as routine costs of a Medicare qualifying clinical trial as provided in NCD 310.1. *See supra* at 35–37. If they are, LCD 35408's prohibition on Medicare reimbursement for nerve conduction studies in the absence of concurrent electromyography testing is inapplicable because an NCD trumps an LCD.[6]

The evidence the court has already recounted on the element of falsity supporting Relator's claims for Claim-Set Three, *see supra* at 43–44, is also probative on the issue of scienter. Moreover, as a participant in the Medicare program, Dr. Odom had a duty to familiarize himself with the legal requirements for Medicare Part B coverage of the nerve conduction studies he administered pursuant to NCT 01979367. *Heckler*, 467 U.S. at 64. Given all of this, Relator has carried his initial burden to show Dr. Odom submitted Claim-Set Three for payment and/or made a statement leading to such submissions with at least reckless disregard for the truth or falsity of his claims or statement that the nerve-conduction studies were covered by Medicare Part B.

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[6] Dr. Odom contends Relator's reliance on LCD 35048 as evidence in support of his FCA claims pertaining to Claim-Set Three, in effect, constructively amended the Complaint by alleging a new claim, prejudicing him by lack of notice and preventing the Government from making a fully informed decision on whether or not to intervene. This contention is without merit for the simple reason the Complaint references LCD 35048 as a governing LCD which provided guidance on the number of electrodiagnostic studies (*i.e.*, nerve conduction studies and electromyography testing) covered by Medicare Part B. ECF No. 1 at 12. Moreover, although the law is well settled a plaintiff may not raise new claims after discovery has begun without amending his complaint, *U.S. ex rel. Owens v. First Kuwaiti General Trading & Contracting Co.*, 612 F.3d 724, 731 (4th Cir. 2010), Relator did not raise any new claims by relying on LCD 35048 as evidence in support of his FCA claims involving Claim-Set Three.

However, the evidence Dr. Odom proffered on the issue of falsity, when viewed in the light most favorable to him, is sufficient to create a genuine issue of material fact on the issue of scienter.

In summary, Relator is not entitled to summary judgment in his favor on Claim-Set Three.

B. Dr. Odom's Motion for Summary Judgment.

In support of his motion for summary judgment on Claim-Set Three, Dr. Odom basically makes two arguments: (1) the CMS data underlying Claim-Set Three cannot be authenticated; and (2) his Clinical Trial Defense is dispositive. Viewing the record in the light most favorable to Relator, as we must in this procedural posture, Dr. Odom is not entitled to summary judgment on Claim-Set Three. First, Dr. Odom admits 624 claims were submitted to the Government under CPT Code 95909 for Medicare reimbursement of five or six nerve conduction studies he performed on a total of 105 patients in 2016. ECF Nos. 1 at 14, 49 at 8; *Medicare Physician & Other Practitioners – by Provider and Service*, https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-provider-and-service/data/2016 (last visited October 28, 2021). Second, the publicly available CMS data shows they were submitted under Dr. Odom's Medicare NPI. *Medicare Physician & Other Practitioners – by Provider and Service*, https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-provider-and-service/data/2016 (last visited October 28, 2021). All of this is sufficient to create a genuine issue of material fact regarding the accuracy of the CMS data at issue. And as far as Dr. Odom's Clinical trial defense is concerned, for the reasons previously outlined, viewing the

evidence in the light most favorable to Relator compels the conclusion a genuine dispute of material fact exists on this issue as well. *See supra* at 41-42.

In summary, Dr. Odom is not entitled to summary judgment on Claim-Set Three.

VIII. Claim-Set Four

Relator does not move for summary judgment with respect to Claim-Set Four, ECF No. 52 at 1 n. 1, and neither does he oppose the court granting Dr. Odom's motion for summary judgment on Claim-Set Four, ECF No. 55 at 1 n.1. Accordingly, the court grants Dr. Odom's motion for summary judgment on Claim-Set Four.

IX. CONCLUSION

In conclusion, the court: (1) denies Relator's motion for summary judgment on Claim-Sets One, Two, and Three, ECF No. 52; (2) denies Dr. Odom's motion for summary judgment on Claim-Sets One, Two, and Three, ECF No. 53; and (3) grants Dr. Odom's motion for summary judgment on Claim-Set Four, ECF No. 53. [7]

s/Cameron McGowan Currie
CAMERON McGOWAN CURRIE
SENIOR UNITED STATES DISTRICT JUDGE

Columbia, South Carolina
October 28, 2021

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[7] The court notes in Dr. Odom's Memorandum in Support of his Motion for Summary Judgment, he requested attorney's fees "due to the frivolous pursuit of this case after discovery documents have demonstrated that Relator's case lacks merit." ECF No. 53-1 at 22. The court will take no action on this request until the ultimate conclusion of this case.